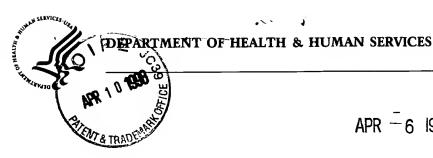
Public Health Service



APR - 6 1998

Food and Drug Administration Rockville MD 20857

> Re: ProstaScint™ Docket No. 97E-0107

APR 1 7 1998

PATENT EXTENSION A/C PATENTS

Stephen G. Kunin Deputy Assistant Commissioner for Patent Policy and Projects Office of the Assistant Commissioner for Patents U.S. Patent and Trademark Office Crystal Park Building 2, Suite 919 Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,162,504 filed by Cytogen Corporation under 35 U.S.C. § 156. The patent claims the human biological product ProstaScint™ (capromab pendetide), Product License Application PLA 95-0041.

In the July 21, 1997, issue of the Federal Register (62 Fed. Reg. 39002), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before January 20, 1998, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs

cc:

W. Scott McNees Cytogen Corporation 600 College Road East Princeton, NJ 08540